

[illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible][illegible]

METHOD AND APPARATUS FOR MANUFACTURING AN
ENDOVASCULAR GRAFT SECTION

RELATED APPLICATIONS

This application is related to U.S. Patent Application Serial No.

_____ entitled "Method and Apparatus for Shape Forming
Endovascular Graft Material", by Chobotov, et al., U.S. Patent Application Serial
No. _____ entitled "Endovascular Graft Joint and Method for
Manufacture", by Chobotov et al., and U.S. Patent Application Serial No.

_____ entitled "Advanced Endovascular Graft", by Chobotov et al.

All of the above applications are commonly owned and were filed on even date
herewith. All of the above applications are hereby incorporated by reference,
each in their entirety.

BACKGROUND

Embodiments of the device and method discussed herein relate to a
system and method for manufacturing intracorporeal devices used to replace,
strengthen, or bypass body channels or lumens of patients; in particular, those
channels or lumens that have been affected by conditions such as abdominal
aortic aneurysms.

Existing methods of treating abdominal aortic aneurysms include invasive
surgical methods with grafts used to replace the diseased portion of the artery.

Although improvements in surgical and anesthetic techniques have reduced perioperative and postoperative morbidity and mortality, significant risks associated with surgical repair (including myocardial infarction and other complications related to coronary artery disease) still remain.

5 Due to the inherent hazards and complexities of such surgical procedures, various attempts have been made to develop alternative repair methods that involve the endovascular deployment of grafts within aortic aneurysms. One such method is the non-invasive technique of percutaneous delivery of grafts and stent-grafts by a catheter-based system. Such a method is described by
10 Lawrence, Jr. et al. in "Percutaneous Endovascular Graft: Experimental Evaluation", Radiology (1987). Lawrence et al. describe therein the use of a Gianturco stent as disclosed in U.S. Patent No. 4,580,568 to Gianturco. The stent is used to position a Dacron® fabric graft within the vessel. The Dacron® graft is compressed within the catheter and then deployed within the vessel to be
15 treated.

A similar procedure is described by Mirich et al. in "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study," Radiology (1989). Mirich et al. describe therein a self-expanding metallic structure covered by a nylon fabric, the structure being anchored by barbs at the proximal and distal
20 ends.

An improvement to percutaneously delivered grafts and stent-grafts results from the use of materials such as expanded polytetrafluoroethylene (ePTFE) for a

pattern. In some embodiments, the stylus may be spring-loaded or actuated in a lateral direction, axial direction, or both.

One particular embodiment of the seam forming apparatus includes at least five motors controlled by a preprogrammed database using automated techniques such as computer numerical control (CNC) which are coupled to the mount system and configured to move the mount system relative to the stylus in a different degree of freedom for each motor. This embodiment, as well as the embodiments described above, and others, allows the operator to reliably form a section of an endovascular graft or other device in an automated or semi-automated manner.

In use, the operator places the layers of fusible material from which an endovascular graft will be formed onto the mount system. The preprogrammed database then controls the movement of the stylus tip so that a pattern of seams are formed in the layers of fusible material to form the desired inflatable channels or any other desirable configuration. As discussed above, such a system is conducive to automation of the seam forming process and can generate significant time and cost savings in the production of endovascular grafts as well as other similar devices. Such a system also generates accuracy and repeatability in the manufacture of such medical devices.

In one embodiment of a method for forming a section of an endovascular graft, or the like, a first layer of fusible material is disposed onto a shape forming member or mandrel. A second layer of fusible material is then disposed onto at

fusible material. The inflatable channel is then expanded and the material forming the inflatable channel fixed when the channel is in an expanded state.

In one embodiment, melt-processible materials can be disposed on or adjacent the expandable member and first layer of fusible material prior to placing the additional layer of fusible material onto the first layer. Use of such a material (e.g., FEP, PFA, etc.) can facilitate adhesion between the layers of fusible material and serves a strain relief function for any dynamic interaction between the expandable member and the endovascular graft section made from the layers of fusible material. In some embodiments, the expandable member can be a connector ring which is configured to be secured to an expandable stent. The expandable member can also be an expandable stent or the like.

These and other advantages of embodiments of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a layer of fusible material being positioned onto a shape forming mandrel.

FIG. 2 shows a first layer of fusible material disposed on a shape forming mandrel.

FIG. 2A is a transverse cross sectional view of the first layer of fusible material and the shape forming mandrel of FIG. 2 taken along lines 2A-2A in FIG. 2.

FIG. 3 illustrates an additional layer of fusible material being deposited onto a shape forming mandrel.

FIG. 4 shows the first layer of fusible material being trimmed by an instrument.

FIG. 5 is a transverse cross sectional view of the layers of fusible material and shape forming mandrel of FIG. 5 taken along lines 5-5 of FIG. 4.

FIG. 6 illustrates additional layers of fusible material being deposited on the shape forming mandrel.

FIG. 7 illustrates an inflation line being positioned on the first and additional layers of fusible material of FIG. 6.

FIGS. 7A and 7B illustrate the formation of the inflation line of FIG. 7.

FIG. 8 shows two expandable members positioned on the layers of fusible material of FIG. 7.

FIG. 9 illustrates the deposition of an adhesive or melt processible material adjacent a connector member of the graft body section under construction.

FIG. 10 shows another additional layer of fusible material being deposited onto the graft body section.

FIG. 11 illustrates excess fusible material being trimmed from the first end and second end of the graft body section adjacent the connector members.

FIG. 12 is an elevational view of the graft body section with the fusible material trimmed away and removed.

FIG. 13A is a side view from the right hand side of a five axis seam forming apparatus.

5 FIG. 13B is a side view from the left hand side of a five axis seam forming apparatus.

FIG. 13C is a front view of the five axis seam forming apparatus of FIGS. 13A and 13B.

FIG. 13D shows a stylus tip in contact with a transverse cross sectioned
10 view of a cylindrical shape forming member with an axis of the stylus tip oriented at an angle with the tangent of the shape forming member at the point of contact therebetween.

FIG. 13E illustrates a stylus tip in contact with a plurality of layers of fusible material in a substantially flat configuration with the longitudinal axis of the stylus
15 tip at an angle with respect to a line which is orthogonal to the surface of the layers.

FIG. 13F is a front view of the seam forming apparatus with a shape forming mandrel and a graft body section on the shape forming mandrel positioned in the chuck of the seam forming member mount system.

20 FIG. 13G illustrates a distal extremity or tip of a stylus in contact with the layers of fusible material of the graft body section.

FIG. 13H illustrates the tip of a stylus in contact with layers of fusible material of the graft body section, forming a seam in the layers.

FIG. 14 shows inflation channels being formed in the layers of fusible material on the shape forming mandrel by the seam forming apparatus stylus tip.

FIG. 15 shows the graft body section with the channel formation complete and pressurized fluid being injected into an inflatable channel network in order to expand the inflatable channels.

FIG. 16A illustrates one half of an embodiment of a two-piece mold for use during expansion of the inflatable channels formed by the seam forming apparatus.

FIG. 16B is an end view showing the shape forming mandrel and graft body section within both halves of the mold.

FIG. 16C shows the graft body section and shape forming mandrel disposed within the mold cavity (with one half of the mold removed for clarity of illustration) with a fluid being injected into the inflatable channels of the graft body section in order to keep the inflatable channels in an expanded state during the fixing or sintering of the fusible material.

FIG. 17 illustrates an outer layer or layers of fusible material being forced into the mold cavity of a portion of the mold by pressurized fluid as indicated by the dotted line.

FIG. 18 is an elevational view in partial section of an embodiment of an inflatable endovascular graft of the present invention.

FIG. 19 is an enlarged view of the graft of FIG. 18 taken at the dashed circle indicated by numeral 19 in FIG. 18.

FIG. 20 is an enlarged view in section taken along lines 20-20 in FIG. 18.

FIG. 21 is a transverse cross sectional view of the graft of FIG. 18 taken
5 along lines 21-21 in FIG. 18.

FIG. 22 is a transverse cross sectional view of the graft of FIG. 18 taken
along lines 22-22 in FIG. 18.

FIG. 23 is a transverse cross sectional view of the graft of FIG. 18 taken
along lines 23-23 in FIG. 18.

DETAILED DESCRIPTION

FIG. 1 illustrates a sheet of fusible material 10 stored on an elongate drum
11. The drum 11 is rotatable, substantially circular in transverse cross section
and has a transverse dimension in the longitudinal center 12 that is greater than
15 the transverse dimension of either end of the drum. The sheet of fusible material
10 is being rolled from the elongate drum in a single layer 13 onto an interior
surface support means in the form of a cylindrical or tapered (conical) shape
forming member or mandrel 14 to form a body section 15 of an endovascular
graft 16. The body section 15 has a proximal end 17 and a distal end 18. For the
20 purposes of this application, with reference to endovascular graft devices, the
proximal end 17 describes the end of the graft that will be oriented towards the
oncoming flow of bodily fluid, usually blood, when the device is deployed within a

conduit of a patient's body. The distal end 18 of the graft is the end opposite the proximal end.

A single layer of fusible material 13 is a term that generally refers to a sheet of material that is not easily separated by mechanical manipulation into additional layers. The shape forming mandrel 14 is substantially cylindrical in configuration, although other configurations are possible. Middle section 20 of mandrel 14 shown in FIGS. 1-2 has a transverse dimension which is smaller than the transverse dimension of a first end section 21 and a second end section 22. The shape forming mandrel may have a first tapered section 23 at the first end and a second tapered section 24 at the second end. The sheet of fusible material 10 is shown being rolled off the elongate drum 11 in the direction indicated by the arrow 11A with the lead end 25 of the first layer of fusible material 10 oriented longitudinally along an outside surface 14A of the shape forming mandrel 14.

The fusible material in the embodiment illustrated in FIG. 1 is ePTFE that ranges from about 0.0005 to about 0.010 inch in thickness; specifically from about 0.001 to about 0.003 inch in thickness. The sheet being disposed or rolled onto the shape forming mandrel 14 may range from about 2 to about 10 inches in width; specifically, from about 3 to about 7 inches in width, depending on the indication and size of the end product.

The ePTFE material sheet 10 in FIG. 1 is a fluoropolymer with a node and fibril composition with the fibrils oriented in primarily a uniaxial direction

substantially aligned with the longitudinal axis of shape forming mandrel 14. Other nodal/fibril orientations of ePTFE could also be used for this layer, including multiaxially oriented fibril configurations or uniaxial material oriented substantially circumferentially about shape forming mandrel 14 or at any desired angle
5 between substantial alignment with the longitudinal axis and substantial alignment with a circumferential line about the shape forming mandrel 14. Uniaxially oriented ePTFE materials tend to have greater tensile strength along the direction of fibril orientation, so fibril orientation can be chosen to accommodate the greatest stresses imposed upon the finished product for the
10 particular layer, combination of layers, and portion of the product where such stress accommodation is needed.

The layers of fusible material made of ePTFE are generally applied or wrapped in an unsintered state. By applying the ePTFE layers in an unsintered or partially sintered state, the graft body section 15, upon completion, can then be
15 sintered or fixed as a whole in order to form a cohesive monolithic structure with all contacting surfaces of ePTFE layers achieving some level of interlayer adhesion. It may, however, be desirable to apply some layers of fusible material that have been pre-sintered or pre-fixed in order to achieve a desired result or to assist in the handling of the materials during the construction process. For
20 example, it may be desirable in some embodiments to sinter the single layer 13 of fusible material applied to the shape forming mandrel 14 in order to act as a better insulator between the shape forming mandrel 14, which can act as a

significant heat sink, and subsequent layers of fusible material which may be welded by seam formation in some locations in order to create inflatable channels.

The amount of expansion of the ePTFE material used for the construction of endovascular grafts and other devices can vary significantly depending on the desired characteristics of the material and the finished product. Typically, the ePTFE materials processed by the devices and methods discussed herein may have a density ranging from about 0.4 to about 2 grams/cc; specifically, from about 0.5 to about 0.9 grams/cc. The nodal spacing of the uniaxial ePTFE material may range from about 0.5 to about 200 microns; specifically, from about 5 to about 35 microns. The nodal spacing for multiaxial ePTFE material may range from about 0.5 to about 20 microns; specifically, from about 1 to about 2 microns.

Although FIG. 1 illustrates a layer of fusible material that is made of ePTFE, the methods described herein are also suitable for a variety of other fusible materials. Examples of other suitable fusible materials for endovascular graft construction and other applications include PTFE, porous PTFE, ultra high molecular weight polyethylene, polyesters, and the like.

FIGS. 2 and 2A depict a first layer of fusible material 26 disposed on the shape forming mandrel 14 with an overlapped portion 27 of the first layer 26 on itself. A terminal end 28 of the first layer 26 is seen extending longitudinally along the length of the shape forming mandrel 14. As the layer of fusible material is

1002557 " 12001
wrapped onto shape forming mandrel 14, some tension may be provided on the
sheet of material by the elongate drum 11. As a result of this tension and the
flexible and conforming properties of the ePTFE material, the first layer of
material 26 conforms closely to the outer contour of the shape forming mandrel
5 14 as is illustrated in FIG. 2.

In some embodiments, it may be desirable to pass the tip of a seam
forming tool or similar device (not shown) along the overlapped portion 27 of first
layer 26 in a longitudinal direction in order to form a seam (not shown) along the
overlapped portion 27 of first layer 26. A tool suitable for forming such a
10 longitudinal seam is a soldering iron with a smooth, rounded tip that will not catch
or tear the layer of fusible material. An appropriate operating temperature for the
tip of such a tool may range from about 320 to about 550 degrees Celsius;
specifically, from about 380 to about 420 degrees Celsius.

FIG. 3 illustrates an additional layer of fusible material 30 being disposed or
15 wrapped onto the first layer of fusible material 26 in a manner similar to that
described above for the first layer 26. Both uniaxial and multiaxial ePTFE may be
used for this additional layer 30. A lead end 31 of the additional layer can be
seen adjacent the terminal end 28 of the first layer 26. Tension on the additional
layer of fusible material 30 helps to make the additional layer 30 conform to the
20 shape forming mandrel 14 as seen in the illustration. Although a single additional
layer 30 is shown in FIG 3 as being disposed onto the first layer 26, it is within the
scope of the invention to wrap multiple additional layers 30 of fusible material in

may be built up onto the proximal end 17 of graft body section 15 on shape forming mandrel 14. The additional end wrap layer or layers 34 may be applied in a manner similar to that of the first layer 26 and additional layers 30 as discussed above.

5 FIG. 7 shows graft body section 15 with the end wrap layer 34 completed with an inflation line 36 disposed on or near the distal end 18 of graft body section 15. The inflation line 36 may be constructed as shown in FIGS. 7A and 7B of ePTFE by wrapping one or more layers of the material about a cylindrical mandrel 37. A longitudinal seam 38 can then be formed in an overlapped portion of the layers by passing the tip of a seam forming tool 39 along the overlapped portion of the first layer in a longitudinal direction in order to form a seam 38 along the overlapped portion of the layers of the inflation line 36. A tool suitable for forming such a longitudinal seam is a soldering iron with a smooth rounded tip that will not catch or tear the layer of fusible material; operating temperatures for the tip may range as previously discussed. Alternatively, the inflation line 36 may be formed using an ePTFE extrusion placed over a mandrel.

10 Once seam 38 is formed in inflation line 36, the fusible material of inflation line 36 may can be fixed or sintered by heating to a predetermined temperature for a predetermined time. For embodiments of the inflation line 36 made of ePTFE, the layers are sintered by bringing the layered assembly to a temperature ranging from about 335 to about 380 degrees Celsius (for unsintered material) and about 320 to about 380 degrees Celsius (for sintering material that was

previously sintered) and then cooling the assembly to a temperature ranging from about 180 to about 220 degrees Celsius. The inflation line 36 may then be removed from mandrel 37 and disposed on a graft body assembly 40 as shown in FIG. 7. The inflation line 36 may be pre-fixed or pre-sintered to avoid having the inner surfaces of the inflation line 36 stick together during the construction and processing of the graft and possibly block the inflation line 36.

In FIG. 8, expandable members in the form of a proximal connector member 41 and a distal connector member 42 have been disposed onto the graft body section 15 towards the respective graft body section proximal end 17 and distal end 18. The proximal connector member 41 is an elongate flexible metal element configured as a ring, with the ring having a zig-zag or serpentine pattern around the circumference of the ring. The distal connector member 42 can have a similar configuration; note the feature of this element in which an extended apex 44 is disposed over inflation line 36 to further stabilize graft section 15. This configuration allows the connector members 41 and 42 to be radially constrained and radially expanded while maintaining a circular ring configuration. The embodiment of the connector members 41 and 42 shown in FIG. 8 may be constructed of any suitable biocompatible material; most suitable are metals, alloys, polymers and their composites known to have superelastic properties that allow for high levels of strain without plastic deformation, such as nickel titanium (NiTi). Other alloys such as stainless steel may also be used. Connector members 41 and 42 shown are also configured to be self-expanding from a

radially constrained state. The serpentine pattern of the connector members 41 and 42 is disposed over base layers of the graft body section as are connector elements 43 which are disposed on certain apices 44 of the serpentine pattern of the connector members 41 and 42. The embodiments of the connector members 41 and 42 shown in FIG. 8 have been shape formed to lie substantially flat against the contour of the outer surface of the shape forming mandrel 14. Although the embodiment of FIG. 8 illustrates connector members 41 and 42 being disposed upon the graft body section 15, expandable members including stents or the like may be used in place of the connector members 41 and 42.

An optional adhesive or melt-processible material such as FEP or PFA may be deposited adjacent the connector members 41 and 42 prior to the addition of additional layers of fusible material to the graft body section 15, as is shown in FIG. 9. Materials such as FEP or PFA can help the layers of fusible material to adhere to the connector members 41 and 42, to inflation line 36 (in the case of distal member 42), and to each other. In addition, such material may serve to provide strain relief between connector members 41 and 42 and the adhered or bonded layers of fusible material (and inflation line 36) adjacent the wire of the connector members 41 and 42. It has been determined that one of the areas of greatest concentrated stress within an endovascular structure such as that described herein, when deployed within a dynamic biological system, such as an artery of a human patient, is at the junction between the connector members 41 and 42 and graft body section 15. Therefore, it may be desirable to include

materials such as FEP or PFA or some other form of strength enhancement or strain relief in the vicinity of this junction.

An outer overall wrap layer 50 may thereafter be applied to the graft body section 15 and connector members 41 and 42 as shown in FIG. 10. The outer overall wrap layer 50 can include one, two, three or more layers of multiaxial ePTFE, usually about 2 to about 4 layers, but uniaxial ePTFE other suitable fusible materials, fibril orientation and layer numbers could also be used. The outer overall wrap layer 50 is most usefully applied under some tension in order for the layer or layers to best conform to the outer contour of the shape forming mandrel 14 and graft body section 15. When the outer layer 50 comprises multiaxial ePTFE, there is generally no substantially preferred orientation of nodes and fibrils within the microstructure of the material. This result in a generally isotropic material whose mechanical properties, such as tensile strength, are generally comparable in all directions (as opposed to significantly different properties in different directions for uniaxially expanded ePTFE). The density and thickness of the multiaxial material can be the same as or similar to those dimensions discussed above.

Although not shown in the figures, we have found it useful to add one or more optional cuff-reinforcing layers prior to the addition of an overall wrap layer 50 as discussed below in conjunction with FIG. 10. Typically this cuff-reinforcing layer is circumferentially applied to graft body section 15 at or near the graft body section proximal end 17 so to provide additional strength to the graft body section

proximal end 17 in those designs in which a proximal cuff (and possibly a proximal rib) are used. Typically the graft experiences larger strains during fabrication and in service in the region of the proximal cuff, especially if a larger cuff is present. This optional cuff-reinforcing layer typically is multiaxial ePTFE, although uniaxial ePTFE and other materials may be used as well. We have found effective a cuff-reinforcing layer width from about 20 to about 100 mm; specifically, about 70 mm. Functionally, however, any width sufficient to reinforce the proximal end of graft body section 15 may be used.

Once the additional layer or layers of fusible material and additional graft elements such as the connector members 41 and 42 and inflation line 36 have been applied, any excess fusible material may be trimmed away from the proximal end 17 and distal end 18 of graft body section 15. FIG. 11 illustrates one or more layers of fusible material being trimmed from the proximal end 17 and distal end 18 of the graft body section 15 so as to leave the connector members 41 and 42 embedded between layers of fusible material but with the connector elements 43 exposed and a distal end 51 of the inflation line 36 exposed as shown in FIG. 12. Once the fusible material has been trimmed from the proximal end 17 and the distal end 18, as discussed above, an additional process may optionally be performed on the proximal end 17, distal end 18 or both the proximal end and distal end 17 and 18. In this optional process (not shown in the figures), the outer wrap 50 is removed from a portion of the connector members 41 and 42 so as to expose a portion of the connector

100227-255200

members 41 and 42 and the additional layer of fusible material 30 beneath the connector member 42 and the proximal end wrap 34 beneath connector member 41. Once exposed, one or more layers of the additional layer or layers 30 or proximal end wrap 34 may have cuts made therein to form flaps which can be folded back over the respective connector members 42 and 41 and secured to form a joint (not shown). One or more layers of fusible material can then be disposed over such a joint to provide additional strength and cover up the joint. The construction of such a joint is discussed in copending U.S. Patent Application "Endovascular Graft Joint and Method for Manufacture" by Chobotov et al. which has been incorporated by reference herein.

Once the graft body section 15 has been trimmed, the entire shape forming mandrel 14 and graft body section 15 assembly is moved to a seam forming apparatus 52 illustrated in FIGS. 13A-13H. This seam forming apparatus 52 has a base 53 and a vertical support platform 54 which extends vertically upward from the back edge of the base 53. A mount system 55 is secured to the base 53 and for the embodiment shown in the figures, consists of a motor drive chuck unit 56 secured to a riser 57 and a live center unit 58 secured to a riser 59. Both risers 57 and 59 are secured to the base 53 as shown. The axis of rotation 55A of the chuck 60 of the motor drive chuck unit 56 and the axis of rotation 55B of the live center 61 of the live center unit 58 are aligned or concentric as indicated by dashed line 55C. A motor is mechanically coupled to the chuck 60 of the motor drive chuck unit 56 and serves to rotate the chuck 60 in a controllable manner.

A vertical translation rack 62 is secured to the vertical support platform 54 and extends from the base 53 to the top of the vertical support platform 54. A vertical car 63 is slidingly engaged on the vertical translation rack 62 and can be moved along the vertical translation rack 62, as shown by arrows 63A, in a controllable manner by a motor and pinion assembly (not shown) secured to the vertical car 63. A horizontal translation rack 64 is secured to the vertical car 63 and extends from the left side of the vertical car 63 to the right side of the vertical car 63. A horizontal car 65 is slidingly engaged on the horizontal translation rack 64 and can be moved along the horizontal rack 64, as shown by arrow 64A, in a controllable manner by a motor and pinion assembly (not shown) which is secured to the horizontal car 65.

A stylus rotation unit 66 is slidably engaged with a second horizontal translation rack 65A disposed on the horizontal car 65 and can be moved towards and away from the vertical car 63 and vertical support platform 54 in a controllable manner as shown by arrow 66A. A stylus rotation shaft 67 extends vertically downward from the stylus rotation unit 66 and rotates about an axis as indicated by dashed line 67B and arrow 67A in a controllable manner. A stylus mount 68 is secured to the bottom end of the rotation shaft 67 and has a main body portion 69 and a stylus pivot shaft 70. A stylus housing 71 is rotatably secured to the stylus mount 68 by the stylus pivot shaft 70. A torsion spring 72 is disposed between the proximal end of the stylus housing 73 and the stylus mount 68 and applies a predetermined amount of compressive, or spring-loaded force to

generating a bifurcated graft body section could be navigated by the five axis seam forming apparatus illustrated herein, as well as other shapes. Finally, seam forming apparatus 52 illustrated herein is but one of a number of devices and configurations capable of achieving the seams of the present inventions.

5 FIG. 13D illustrates an enlarged view of a stylus tip 75 applied to a rotating cylindrical surface 86B with the surface rotating in a counterclockwise direction as indicated by arrow 86A. The cylindrical surface can support one or more layers of fusible material (not shown) between the distal extremity 80 of the stylus tip 75 and the surface 86B which require seam to be formed therein. The stylus tip 75 has a longitudinal axis that forms an angle 86 with a tangent to the surface of the cylindrical surface indicated by dashed line 87. Although not necessary, we have found it useful to have the object in contact with the stylus tip 75 rotating or moving in a direction as show in FIG. 13D, relative to angle 86 in order to prevent chatter of the configuration or distortion of fusible material on the surface 86A. In
10
15 one embodiment, angle 86 may range from about 5 to about 60 degrees; specifically, from about 10 to about 20 degrees. It is also useful if the distal extremity 80 of the stylus tip 75 has a smooth surface and is radiused. A suitable radius for one embodiment may range from about 0.01 to about 0.030 inch; specifically, from about 0.015 to about 0.02 inch.

20 FIG. 13E shows a similar relationship between a stylus tip 75 and hard surface 81. Surface 81 may have one or more layers of fusible material (not shown) disposed thereon between distal extremity 80 and surface 81. A

T
E
S
T
I
N
G
S
E
C
T
I
O
N

longitudinal axis 75A of stylus tip 75 forms an angle 86 with the dashed line 89 that is parallel to surface 81. Angle 88 in this embodiment should range from about 5 to about 60 degrees; specifically, from about 10 to about 20 degrees, so to ensure smooth relative motion between surface 81 and tip 75. The surface 81 is shown moving relative to the stylus tip 75 in the direction indicated by arrow 81A.

The pressure exerted by the extremity 80 of stylus tip 75 on the material being processed is another parameter that can affect the quality of a seam formed in layers of fusible material. In one embodiment in which the stylus tip is heated, the pressure exerted by the distal extremity 80 of the stylus tip 75 may range from about 100 to about 6,000 pounds per square inch (psi); specifically, from about 300 to about 3,000 psi. The speed of the heated stylus 75 relative to the material being processed, such as that of graft body section 15, may range from about 0.2 to about 10 mm per second, specifically, from about 0.5 to about 1.5 mm per second. The temperature of the distal extremity 80 of the heated stylus tip 75 in this embodiment may range from about 320 to about 550 degrees Celsius; specifically, about 380 to about 420 degrees Celsius.

Seam formation for ePTFE normally occurs by virtue of the application of both heat and pressure. The temperatures at the tip of the heated stylus 75 during such seam formation are generally above the melting point of highly crystalline ePTFE, which may range be from about 327 to about 340 degrees Celsius, depending in part on whether the material is virgin material or has

previously been sintered). In one embodiment, the stylus tip temperature for ePTFE welding and seam formation is about 400 degrees Celsius. Pressing such a heated tip 75 into the layers of ePTFE against a hard surface such as the outside surface of the shape forming mandrel) compacts and heats the adjacent layers to form a seam with adhesion between at least two of, if not all, the layers. At the seam location and perhaps some distance away from the seam, the ePTFE generally transforms from an expanded state with a low specific gravity to a non-expanded state (i.e., PTFE) with a relatively high specific gravity. Some meshing and entanglement of nodes and fibrils of adjacent layers of ePTFE may occur and add to the strength of the seam formed by thermal-compaction. The overall result of a well-formed seam between two or more layers of ePTFE is adhesion that can be nearly as strong or as strong as the material adjacent the seam. The microstructure of the layers may change in the seam vicinity such that the seam will be impervious to fluid penetration.

It is important to note that a large number of parameters determine the proper conditions for creating the fusible material seam, especially when that material is ePTFE. Such parameters include, but are not limited to, the time the stylus tip 75 is in contact with the material (or for continuous seams, the rate of tip movement), the temperature (of the tip extremity 80 as well as that of the material, the underlying surface 81, and the room), tip contact pressure, the heat capacity of the material, the mandrel, and the other equipment, the characteristics of the material (e.g. the node and fibril spacing, etc.), the number of material

layers present, the contact angle between the tip extremity 80 and the material, the shape of the extremity 80, etc. Knowledge of these various parameters is useful in determining the optimal combination of controllable parameters in forming the optimal seam. And although typically a combination of heat and pressure is useful in forming an ePTFE seam, under proper conditions a useful seam may be formed by pressure at ambient temperature (followed by elevation to sintering temperature); likewise, a useful seam may also be formed by elevated temperature and little-to-no applied pressure.

For example, we have created seams in ePTFE that formed an intact, inflatable cuff by the use of a clamshell mold that presented an interference fit on either side of a cuff zone for the ePTFE. The application of pressure alone without using an elevated temperature prior to sintering formed a seam sufficient to create a working cuff.

FIG. 13F depicts a front view of the seam forming apparatus 52 with a shape forming mandrel 14 secured to the chuck 60 and the live center unit 58. The distal extremity of the heated stylus tip 75 is in contact with the graft body section 15 which is disposed on the shape forming mandrel 14. The chuck 60 is turning the shape forming mandrel 14 and graft body section 15 in the direction indicated by the arrow 60A to form a seam 81 between the layers of fusible material of the graft body section 15.

FIGS. 13G and 13H illustrate an enlarged view of the heated stylus tip 75 in contact with the graft body section 15 in the process of creating one or more

seams 81 which are configured to form elongate inflatable channels 82 in the graft body section 15. The term "inflatable channels" may generally be described herein as a substantially enclosed or enclosed volume between layers of fusible material on a graft or graft section, and in some embodiments, in fluid communication with at least one inlet port for injection of inflation material. The enclosed volume of an inflatable channel or cuff may be zero if the inflatable cuff or channel is collapsed in a non-expanded state. The enclosed volume of an inflatable channel may or may not be collapsible during compression or compacting of the graft body section 15.

FIG. 13H is an enlarged view in section of the distal extremity 80 of the heated stylus tip 75 in contact with layers of fusible material of graft body section 15. The layers of fusible material are being heated and compressed to form a bond 15A therebetween. The seam forming apparatus can position the distal extremity 80 at any desired location on the graft body section 15 by activation of one or more of the five motors controlled by the components in the control unit housing 77. Each of the five motors controls relative movement between graft body section 15 and distal extremity 80 in one degree of freedom. Thus, the distal extremity 80 may be positioned above the surface of the graft body section 15, as shown in FIG. 13C, and brought to an appropriate temperature for seam formation, as discussed above, by resistive heating or any other appropriate method. Once extremity 80 has reached the target temperature, it can be lowered by activation of the motor which controls movement of the vertical car.

The extremity 80 can be lowered and horizontally positioned by other control motors until it contacts the graft body section in a desired predetermined position on graft body section 15, as shown in FIG. 13F.

Once distal extremity 80 makes contact with graft body section 15 with the proper amount of pressure, it begins to form a seam between the layers of the fusible material of the graft body section as shown in FIG. 13H. The pressure or force exerted by the extremity 80 on the graft body section may be determined by the spring constant and amount of deflection of torsion spring 72 shown in FIGS. 13A and 13B; generally, we have found a force at the extremity 80 ranging from about 0.2 to about 100 grams to be useful. As the seam formation process continues, the surface of graft body section 15 may be translated with respect to the distal extremity 80 while desirably maintaining a fixed, predetermined amount of pressure between the distal extremity 80 and the layers of fusible material of the graft body section. The CPU (or an equivalent device capable of controlling the components of apparatus 52) of the control unit housing 77 may be programmed, for instance, a mathematical representation of the outer surface contour of any known shape forming member or mandrel.

The CPU is thereby able to control movement of the five motors of apparatus 52, so that distal extremity 80 may follow the contour of the shape forming member while desirably exerting a fixed predetermined amount of pressure the layers of fusible material disposed between the distal extremity 80 and the shape forming member. While seam formation is taking place, the

pressure exerted by the distal extremity 80 on the shape forming member may be adjusted dynamically. The extremity 80 may also be lifted off the graft body section and shape forming member in locations where there is a break in the desired seam pattern. Once distal extremity 80 is positioned above the location of the starting point of the next seam following the break, the extremity 80 may then be lowered to contact the layers of fusible material, reinitiating the seam formation process.

Use of the seam forming apparatus 52 as described herein is but one of a number of ways to create the desired seams in the graft body section 15 of the present invention. Any suitable process and apparatus may be used as necessary and the invention is not so limited. For instance, seams may also be formed in a graft body section 15 by the use of a fully or partially heated clamshell mold whose inner surfaces contain raised seam-forming extensions. These extensions may be configured and preferentially or generally heated so that when the mold halves are closed over a graft body section 15 disposed on a mandrel, the extensions apply heat and pressure to the graft body section directly under the extensions, thereby "branding" a seam in the graft body section in any pattern desired and in a single step, saving much time over the technique described above in conjunction with seam forming apparatus 52.

If the fusible material comprises ePTFE, it is also possible to infuse or wick an adhesive (such as FEP or PFA) or other material into the ePTFE layers such that the material flows into the fibril/node structure of the ePTFE and occupies the

pores thereof. Curing or drying this adhesive material will mechanically lock the ePTFE layers together through a continuous or semi-continuous network of adhesive material now present in and between the ePTFE layers, effectively bonding the layers together.

5 FIG. 14 illustrates a substantially completed set of seams 81 formed in the layers of fusible material of the graft body section 15, which seams form inflatable channels 82. FIG. 15 illustrates graft body section 15 as fluid (such as compressed gas) is injected into the inflation line 36 and in turn into the inflatable channel network 84 of body section 15, as shown by arrow 84A. The fluid is
10 injected to pre-stress the inflatable channels 82 of body section 15 and expand them outward radially. The fluid may be delivered or injected through an optional elongate gas containment means having means for producing a permeability gradient in the form of a manifold or pressure line 85. The pressure line 85 shown in FIG. 15 has a configuration with an input (not shown) located outside
15 the inflation line and a plurality of outlet apertures or orifices (not shown) that may be configured to provide an even distribution of pressure within the inflatable channel network 84. Other fluid injection schemes and configurations are of course possible.

20 Because ePTFE is a porous or semi-permeable material, the pressure of exerted by injected fluids such as pressurized gas tends to drop off or diminish with increasing distance away from the outlet apertures or orifices (not shown) of manifold or pressure line 85. Therefore, in some embodiments, pressure line 85

may comprise apertures or orifices (not shown) which, when disposed in graft body section 15, progressively increases in size as one moves distally along the pressure line towards the proximal end 17 graft body section 15 in order to compensate for a drop in pressure both within the inflatable channel network 84 and within the manifold or pressure line 85 itself.

Once some or all of the inflatable channels 82 have been pre-expanded or pre-stressed, the graft body section 15 and shape forming mandrel assembly 89 may then be positioned within an outer constraint means in the form of a mold to facilitate the inflatable channel expansion and sintering process. One half of a mold 90 suitable for forming an embodiment of a graft body section 15 such as that shown in FIG. 15 is illustrated in FIG. 16A. A mold half body portion 91 is one of two pieces of mold 90. A mold similar to mold 90 could be made from any number of mold body portions configured to fit together. For example, a mold 90 could be designed from three, four, five or more mold body portions configured to fit together to form a suitable main cavity portion 93 for maintaining the shape of graft body section 15 during channel expansion and sintering. For certain configurations, a one-piece mold may be used.

Mold body portion 91 has a contact surface 92 and a main cavity portion 93. Main cavity portion 93 has an inside surface contour configured to match an outside surface contour of the graft body section with the inflatable channels in an expanded state. Optional exhaust channels 92A may be formed in contact

surface 92 and provide an escape flow path for pressurized gas injected into the inflatable channel network 84 during expansion of the inflatable channels 82.

The main cavity portion 93 of the FIGS. 16A-16B embodiment is substantially in the shape of a half cylinder with circumferential channel cavities 94 for forming the various inflatable channels 82 of graft body section 15. Cavity 93 has a first tapered portion 95 at the proximal end 96 of mold 90 and a second tapered portion 97 at the mold distal end 98. FIG. 16B shows an end view of mold 90 with the two mold body portions 91 and 100 pressed together with the assembly of the graft body section 15 and shape forming mandrel 14 disposed mold cavity 93.

FIG. 16C shows the assembly of the graft body section 15 and shape forming mandrel 14 disposed within mold 90, with the circumferential inflatable channels 82 of the graft body section 15 aligned with the circumferential channel cavities 94 of the main cavity portion 93. One mold body portion 100 of mold 90 is not shown for the purpose of clarity of illustration. A pressurized fluid indicated as being delivered or injected into manifold or pressure line 85 by arrow 85A.

FIG. 17 illustrates by the phantom lines how the outer layers 94A of circumferential inflatable channel 82 of the fusible material of a graft body section 15 are expanded into the circumferential channel cavity 94 of mold cavity 93. The direction of the expansion of the outer layers 94A to the position indicated by the phantom lines is indicated by arrow 94B. A cross sectional view of the seams 83 of the circumferential inflatable channel 82 is shown in FIG. 17 as well.

While the graft body section network of inflatable channels 84 is in an expanded state by virtue of pressurized material being delivered or injected into pressure line 85, the entire assembly may be positioned within an oven or other heating device (not shown) in order to bring the fusible material of graft body section 15 to a suitable temperature for an appropriate amount of time in order to fix or sinter the fusible material. In one embodiment, the fusible material is ePTFE and the sintering process is carried out by bringing the fusible material to a temperature of between about 335 and about 380 degrees Celsius; specifically, between about 350 and about 370 degrees Celsius. The mold may then be cooled and optionally quenched until the temperature of the mold drops to about 250 degrees Celsius. The mold may optionally further be quenched (for handling reasons) with ambient temperature fluid such as water. Thereafter, the two halves 91 and 100 of mold 90 can be pulled apart, and the graft assembly removed.

The use of mold 90 to facilitate the inflatable channel expansion and sintering process is unique in that the mold cavity portion 93 acts as a backstop to the graft body section so that during sintering, the pressure created by the injected fluid that tends to expand the inflatable channels outward is countered by the restricting pressure exerted by the physical barrier of the surfaces defining the mold cavity 93. In general terms, therefore, it is the pressure differential across the inflatable channel ePTFE layers that in part defines the degree of expansion of the channels during sintering. During the sintering step, the external pressure

exerted by the mold cavity surface competes with the fluid pressure internal to the inflatable channels (kept at a level to counteract any leakage of fluid through the ePTFE pores at sintering temperatures) to provide an optimal pressure differential across the ePTFE membrane(s) to limit and define the shape and size of the inflatable channels.

Based on this concept, we have found it possible to use alternatives to a mold in facilitating the inflatable channel expansion process. For instance, it is possible inject the channel network with a working fluid that does not leak through the ePTFE pores and to then expand the network during sintering in a controlled manner, without any external constraint. An ideal fluid would be one that could be used within the desired ePTFE sintering temperature range to create the necessary pressure differential across the inflatable channel membrane and the ambient air, vacuum, or partial vacuum environment so to control the degree of expansion of the channels. Ideal fluids are those that possess a high boiling point and lower vapor pressure and that do not react with ePTFE, such as mercury or sodium potassium. In contrast, the network of inflatable channels can also be expanded during the fixation process or sintering process by use of vapor pressure from a fluid disposed within the network of inflatable channels 84. For example, the network of inflatable channels 84 can be filled with water or a similar fluid prior to positioning assembly in the oven, as discussed above. As the temperature of the graft body section 15 and network of inflatable channels 84 begins to heat, the water within the network of inflatable channels 84 begins to

heat and eventually boil. The vapor pressure from the boiling water within the network of inflatable channels 84 will expand the network of inflatable channels 84 provided the vapor is blocked at the inflation line 85 or otherwise prevented from escaping the network of inflatable channels.

5 FIG. 18 shows an elevational view in partial longitudinal section of an endovascular graft assembly 105 manufactured by the methods and with the apparatus described above. Endovascular graft assembly 105 comprises a graft body section 108 with a proximal end 106, a distal end 107, and circumferentially oriented inflatable channels 111 shown in an expanded state. A longitudinal inflatable channel 116 fluidly communicates with the circumferential inflatable channels 111.

10 An expandable member in the form of a proximal connector member 112 is shown embedded between proximal end wrap layers 113 of fusible material. An expandable member in the form of a distal connector member 114 is likewise shown embedded between distal end wrap layers 115 of fusible material. The proximal connector member 112 and distal connector member 114 of this embodiment are configured to be secured or connected to other expandable members which may include stents or the like, which are not shown. In the embodiment of FIG. 18, such a connection may be accomplished via connector elements 117 of the proximal and distal connector members 112 and 114, which extend longitudinally outside of the proximal and distal end wrap layers 113 and 115 away from the graft body section 108.

The FIG. 18 embodiment of the present invention features junction 118 between the distal end wrap layers 115 of fusible material and the layers of fusible material of a distal end 121 of the graft assembly main body portion 122. There is likewise a junction 123 between the proximal end wrap layers 113 and the layers of fusible material of a proximal end 124 of the graft assembly main body portion 122. The junctions 118 and 123 may be tapered, with overlapping portions that are bound by sintering or thermomechanical compaction of the end wrap layers 113 and 115 and layers of the main body portion 122. This junction 123 is shown in more detail in FIG. 19.

In FIG. 19, six proximal end wrap fusible material layers 113 are disposed between three fusible material inner layers 125 and three fusible material outer layers 126 of the main body portion proximal end 124.

FIG. 20 illustrates a sectional view of a portion of the distal connector member 114 disposed within the distal end wrap layers 115 of fusible material. Connector member 114 is disposed between three outer layers 127 of fusible material and three inner layers 128 of fusible material. Optional seams 127A, formed by the methods discussed above, are disposed on either side of distal connector member 114 and mechanically capture the connector member 114. FIG. 21 likewise is a transverse cross sectional view of the proximal connector member 112 embedded in the proximal end wrap layers 113 of fusible material.

FIG. 22 illustrates a transverse cross section of the longitudinal inflatable channel 116 formed between main body portion 122 outer layers 131 and the

main body portion 122 inner layers 132. FIG. 23 is a transverse cross section of graft main body portion 122 showing a circumferential inflatable channel 111 in fluid communication with longitudinal inflatable channel 116. The circumferential inflatable channel 111 is formed between the outer layers 131 of fusible material of main body portion 122 and inner layers 132 of fusible material of main body portion 122.

While particular forms of embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.